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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,882	03/08/2004	David Radunsky	067062.0127	2882

31625 7590 11/28/2006

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EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,882	RADUNSKY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-14 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1,3-6,8-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In each of the independent claims, various plural recitations of "avoids removal of "significant amounts" of immunoglobulins and "similar large molecules" are vague and indefinite as the scope and range of "significant" and of "similar large molecules" are each unclear.

Claims 1,3-6,8-14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no clear concise support for the recitation of "***avoids removal of significant amounts... or "similar large molecules" in the instant Specification. Such recitations therefor all constitute New Matter.***.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotitschke patent 4,900,720 in view of Ash patent 5,919,369 (both of record), newly cited Hoffman et al patent 5,661,124 and newly cited Antwiler patent 4,968,432.

For independent claims 1 & 6, Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the formulation being in solution) that is formulated to treat many toxic diseases [as with instant claims 5 and 10] (column 1 lines 37-45, etc.), and contains albumin (up to 35-50 g/l or more), inflammatory mediators (igG, igA) and other receptor molecules (column 3, lines 35-52). The albumin and other constituents in the replacement fluid medium are rendered "clean", as claimed, by ultrafiltration, exposure to a propriolactone sterilizing substance and exposure to ultraviolet (UV) radiation (column 3, lines 45-51 and several sections of text of column 6, lines 32-66). The albumin and other constitutents also have binding sites operable to attract inflammatory mediators from tissue of the patient. The disclosed solution also contains a balanced amount of salts and other electrolytes (column 6, lines 60-64 and Table concerning "Electrolytes" on column 7).

The claims differ in requiring the albumin molecules to be in sufficient amounts to maintain adequate plasma oncotic pressure during any very large pore hemofiltration that may have occurred. However, Hoffman at column 20, line 64-column 21, line 26 teaches a blood substitution solution that contains from between 0 and 70 g/l of albumin to maintain necessary oncotic pressure in patients. Ash teaches at column 7, lines 1-24 teaches that some amounts of albumin are removed from blood being circulated through large pore hemofiltration and inherently eventually needing replacement. Antwiler teaches blood replacement fluid being added to blood being purified in an extracorporeal blood circuit, downstream from hemofiltration membrane filters and a dialyzing filter, from a discrete source 64 (column 2, lines 43-49 and lines 62-64).

Hence, it would have been obvious to have included sufficient amounts of albumin in the Kotitschke formulation to maintain adequate plasma oncotic pressure in receiving patients, as suggested by Ash, Antwiler and Hoffman, in order to improve the patient's clinical condition; the concentration of albumin in the Kotitschke formulation suggested by Hoffman as generally adequate to maintain such oncotic pressure.

Recitations of the replacement fluid having been intended for use with a blood treatment system containing an ultrafiltration means "which avoids removal of significant amounts of immunoglobulins and similar large molecules" have all been given little patentable weight; since the claims are drawn to a composition of matter or particular fluid composition, the properties of any filtration medium of a system utilizing the composition is immaterial, with no effects on the properties of the composition.

For claims 3,4,8 and 9, the concentration of albumin may fall within the claimed concentration range of between about 0.5 g/100 ml (5g/l) to 20 g/ml (200g/l), (see Kotitschke at column 3, line 38, and Tables at columns 7 & 8 and also Hoffman at column 21, line 14).

For claims 5 and 10, Kotitschke includes replacement receptor and inflammatory mediator molecules (see column 3, lines 29-47 concerning igG, igA, igM and macroglobulin).

Claims 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antwiler patent 4,968,432 in view of Ash patent 5,919,369, Kotitschke patent 4,900,720 and Hoffman et al patent 5,661,124.

With respect to claims 11,12 and 17, Antwiler discloses source or reservoir having plasma colloid replacement fluid 64, coupling and flow line 66,68,71 to connect flow of the fluid with an extracorporeal blood plasma purification circuit 29,56,20 having at least one relatively large pore filter 36 of specific pore size/molecular weight cutoff (column 2, lines 43-45) for removing target molecules. The filter of the Antwiler system can be considered as effective to avoid removal of significant amounts of molecules larger than a given, selected molecular weight or size corresponding to the given selected pore size of the filter. For claims 12-14, Antwiler discloses filter 36 as forming a filtered blood stream 29 and downstream ultrafiltrate stream 56, to which blood replacement fluid is infused from source 64'.

The claims all differ in requiring the replacement fluid to comprise clean albumin and other clean, target receptor molecules. Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the formulation being in solution) that contains albumin (up to 35-50 g/l or more), inflammatory mediators (igG, igA) and other receptor molecules (column 3, lines 35-52). The albumin and other constituents in the replacement fluid medium are rendered "clean", as claimed, by ultrafiltration, exposure to a propriolactone sterilizing substance and exposure to ultraviolet (UV) radiation (column 3, lines 45-51 and several sections of text of column 6, lines 32-66). The albumin and other constitutents also have binding sites operable to attract inflammatory mediators from tissue of the patient. Ash teaches that some amount of albumin is lost during plasmafiltration and hemofiltration, even from very large pore filters (column 7, lines 1-24). Hoffman teaches that albumin is added to replacement blood solutions to maintain oncotic pressure (column 21, lines 7-26). It would have been obvious to have utilized a fluid containing such albumin and other receptor molecules, as the replacement fluid of Antwiler, as taught by Kotitschke, Ash and Hoffman, in order to improve the clinical condition of the patient being treated, maintain adequate oncotic pressure and otherwise keep the patient alive.

Recitations of the replacement fluid having been intended for use with a blood treatment system containing an ultrafiltration means "which avoids removal of significant amounts of immunoglobulins and similar large molecules" have all been given little

patentable weight; since the claimed terminology "similar", "large" and "significant are all relative without definite scope and range

For claim 11, Kotitschke also teaches the obviousness of blood or plasma replacement solutions having balanced amounts of salts and other electrolytes (column 6, lines 56-68 and the Table at column 7) to maintain patient viability and health.

For claims 12-14 and 17, Ash teaches the obviousness of selecting a molecular weight cutoff in the range of 150,000 to 5,000,000 Daltons, for the filter, so as to allow passage of most plasma proteins, while facilitating removal of toxins and other target molecules.

Applicant's arguments filed on October 09, 2006 have been fully considered but they are not persuasive.

With respect to claims 1,3-6 and 8-10, it is argued that Kotitschke has a composition appropriate for use with a plasmapheresis system rather than with a conventional extracorporeal blood circuit. However, since these are composition claims, the type of system with which the composition is utilized is immaterial.

It is further argued that since Kotitschke utilizes a composition that contains immunoglobulins, as essential, it cannot be combined with any reference that discloses removal of immunoglobulins. It is submitted that the instant claims neither preclude presence of immunoglobulins or their absence in the claimed fluid composition.

With respect to claim 11, it is argued that Antiwiler does not disclose any fluid "kit". It is submitted that although the terminology "kit" is not specifically denoted by the

reference, the commonly understood meaning of "kit" is any assembled set of parts or materials. The system of Antwiler contains a plurality of parts and materials.

With respect to claims 11-14 and 17, it is argued that Antiwiler does not disclose use of any "hemofilter". However, Antiwiler does disclose filtering of blood plasma portions, hence hemofiltration (column 1, lines 10-14 and column 2, lines 43-45).

It is then argued that Ash teaches the use of a sorbent suspension, and combination of plasma filtration and hemofiltration, that are not combinable with other art of record. However, the claims are deemed to not exclude combination of different types of filters or use of sorbent suspensions or other compositions, so long as the applied prior art utilizes some form of hemofiltration.

In response to arguments concerning whether Antwiler utilizes albumin in the replacement fluid, it is submitted that Kotitschke and Hoffman were relied upon for teachings of motivation to include albumin in the replacement fluid.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

November 25, 2006

Joseph Drodge
Primary Examiner